



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

The Honorable Richard J. Durbin
United States Senate
Washington, D.C. 20510

MAY 21 1999 6366 99 MAY 24 P1:47

Dear Senator Durbin:

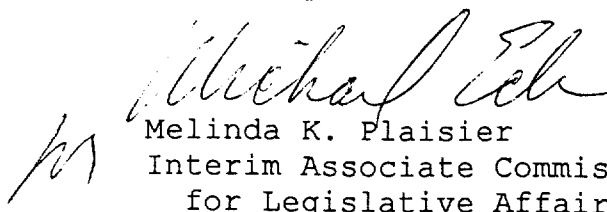
Thank you for your letter of April 21, 1999, concerning the petition for a performance standard for *Vibrio vulnificus* in raw, molluscan shellfish filed with the Food and Drug Administration (FDA or the Agency) by the Center for Science in the Public Interest (CSPI). FDA published a request for comments on this petition in the Federal Register of January 21, 1999.

You urge FDA to approve without delay the request by CSPI for a performance standard for *Vibrio vulnificus* in raw molluscan shellfish. You point out that there are between 10 and 25 deaths annually from *Vibrio vulnificus*, as well as long term injuries to survivors of infections. Since new technologies have been developed that destroy the pathogen while maintaining the taste and texture of raw shellfish, the new technologies can be implemented as part of the seafood Hazard Analysis Critical Control Point system, resulting in safer products benefiting consumers and the industry. You point to savings in economic costs to society from infections that currently exceed by several times the raw shellfish industry's annual sales.

We appreciate your thoughtful comments and we have entered them into the Administrative Record for this petition. They will be considered in the Agency's deliberations on this petition.

We trust this responds to your concerns. If you have further questions about this or any other matter, please do not hesitate to call.

Sincerely,


Melinda K. Plaisier
Interim Associate Commissioner
for Legislative Affairs

cc: HFA-305 (Docket No 98P-0504)

98P-0504

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RICHARD J. DURBIN
ILLINOIS

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April 28, 1999

Jane E. Henney, M.D.
Commissioner
Food and Drug Administration
Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Henney:

I am writing to urge your support for the request by the Center for Science in the Public Interest (CSPI) that the Food and Drug Administration (FDA) establish a performance standard for *Vibrio vulnificus* in raw molluscan shellfish harvested from waters that have been linked to illnesses from this organism. The performance standard requested by CSPI would do much to improve the safety of these products. I therefore urge FDA to act on this citizen petition without delay.

While the problem with *Vibrio vulnificus* is limited to shellfish harvested in warm waters, these shellfish are widely distributed. Since 1989, raw shellfish harboring *Vibrio vulnificus* have sickened or killed over 200 consumers in 19 states, including one in Illinois. Year after year, anywhere from 10 to 25 people die after eating contaminated shellfish, and those who survive can suffer debilitating injuries, requiring amputation and long-term rehabilitation.

New technologies have been developed that destroy the deadly pathogen while maintaining the taste and texture of raw shellfish. By establishing a performance standard requiring that shellfish intended for raw consumption and harvested from waters linked to illnesses contain nondetectable levels of viable *Vibrio vulnificus*, FDA can ensure that processors take advantage of the new technologies during those times of the year when the pathogen is present at high levels in harvested raw shellfish. These new technologies could be easily implemented as part of FDA's new seafood HACCP system, which so far has proven ineffective in addressing the problem of *Vibrio vulnificus* contamination in raw shellfish. HACCP systems work best when linked with a strong standard. The result would be significantly safer products, benefitting both consumers and the raw shellfish industry: consumers would be assured that they are purchasing only raw shellfish that are free from *Vibrio vulnificus*, while industry would see a concomitant increase in demand for its products and a decrease in its liability exposure.

Adoption of the requested performance standard would yield tremendous economic

No. 99-3069

Commissioner Jane E. Henney

April 21, 1999

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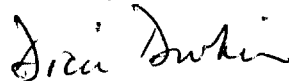
benefits. FDA has estimated that *Vibrio vulnificus* infections cost society approximately \$120 million per year. When the potential economic benefit of eliminating all or most of these cases is weighed against the size of the warm water, raw shellfish industry's annual sales, recently estimated at \$36 million, it becomes evident that the proposed performance standard is economically sound.

Moreover, the slight increase in production costs associated with post-harvest treatment of shellfish to eliminate *Vibrio vulnificus* could readily be passed on to consumers, because the prices of raw shellfish harvested from warm waters would remain competitive with those for raw shellfish harvested from other coastal waters.

FDA should act quickly to establish a performance standard for *Vibrio vulnificus* in raw shellfish that will protect the health of consumers throughout the country. Such action is critical if the agency is to fulfill its public-health mission.

Thank you for your consideration in this matter.

Sincerely,

A handwritten signature in dark ink, appearing to read "Dick Durbin", written in a cursive style.

Richard J. Durbin
United States Senator